UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OKLAHOMA

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 19-CR-58-JED
	)	
GREGORY SINCLAIR CONNOR,	)	
	)	
Defendant.	)	

DEFENDANT'S PROPOSED JURY INSTRUCTIONS

COMES NOW the Defendant, Gregory Sinclair Connor, by and through his attorneys of record, Mark D. Lyons and Martha L. Blackburn of Lyons & Clark, Inc., and for his proposed jury instructions, hereby submits the following:

Respectfully submitted,

/s/ Mark D. Lyons
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PROPOSED JURY INSTRUCTION NO.____
RECEIPT OF MISBRANDED DRUG IN INTERSTATE COMMERCE

The Government has charged Dr. Connor in Count 2 of the second superceding indictment with receipt of misbranded drugs in interstate commerce pursuant to Title 21 USC §331(c). That statute reads as follows:

The following acts and the causing thereof are hereby prohibited:

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

PROPOSED JURY INSTRUCTION NO. ___
MISBRANDED DRUG DEFINED

The Government has charged Dr. Connor with a scheme and artifice to defraud his patients by using misbranded drugs. Misbranding is defined as:

A drug or device shall be deemed to be misbranded--

(a) False or misleading label.

(1) If its labeling is false or misleading in any particular.

For the purposes of this Act

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act [21 USCS §§ 301 et seq.] that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

m) The term "labeling" means all labels and other written, printed, or graphic matters (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the articles to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual."

Source: Title 21 U.S.C. §301, §331 and §352.

PROPOSED JURY INSTRUCTION NO.
PROOF OF INTENT TO DEFRAUD REGARDING MISBRANDED DRUGS

The mere act of receiving a misbranded drug in interstate commerce is not a violation of 21 USC §331(c) and 21 USCS § 331. The Government is required to prove beyond a reasonable doubt Dr. Connor had the specific intent to defraud or mislead his patients knowingly using misbranded drugs.

The Government must prove beyond a reasonable doubt Dr. Connor acted with the intent to defraud or mislead the patient or patients, for whom the misbranded drug was purchased and delivery or proffered delivery thereof to the patient for pay or otherwise.

The Government must further prove the intent to mislead or defraud requires proof his patients would actually or reasonably rely on materially false statements Dr. Connor about Botox made to his patients.

Sources:

United States v. Watkins, 278 F.3d 961, 966 (9th Cir., 2002), citing to *Neder v. United States*, 527 U.S. 1, 144 L. Ed. 2d 35, 119 S. Ct. 1827 (1999).

"Section 303 of the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 333(a)(2), imposes felony liability for misbranding "with the intent to defraud or mislead." The question presented is whether this provision requires proof of materiality. We hold that materiality must be proven as an element of the offense under either a theory of intent to defraud or a theory of intent to mislead." *Watkins*, p. 963.

"Our examination of the plain meaning of this phrase as well as its settled meaning under the common law lead us to conclude that an intent to mislead also requires proof of materiality. That is, regardless of any additional liability Congress intended to include with this language, one still

cannot 'intend to mislead' another by means of a misrepresentation without having an expectation that the recipient would actually or reasonably rely on it." *Id.*, at p. 966.

See ¶ 21 of the Second Superceding Indictment which claims that FDA approved Botox must contain a "Medication Guide" with warnings for **patients** for when to call a doctor.

See also ¶ 32 of the Second Superceding Indictment which claims, "**CONNOR** did not disclose to his patients at the Clinic that he was illegally treating them with illegal foreign Botox purchased from foreign distributors." (emph. in original)

United States v. Patwardhan, 2009 U.S. Dist. LEXIS 66051, *29-*31 (C.D. Cal., July 18, 2009) "Assuming, arguendo, the Government was required to prove Defendant specifically intended to defraud or **mislead his patients** as to adequacy of directions for use of the drugs or as to the comprehensibility of the labels or labeling on the drugs, the Government met its burden of proof." (emph. added)

See also *United States v. Mitcheltree*, 940 F.2d 1329, 1355 (10th Cir. 1991). "Returning to MDMA counts one and four, we hold that while sufficient evidence exists concerning defendant's intent to **mislead or defraud consumers**, by no means does the record contain sufficient evidence of **misleading or defrauding a government agency**." (emph. added)

PROPOSED JURY INSTRUCTION NO.____
EXCEPTIONS TO LABELING REQUIREMENTS

An exception to the requirement of properly labeling a drug applies in certain circumstances. A drug is exempt from the labeling requirements in §301 if:

A drug subject to the requirements of section 503(b)(1) of the act shall be exempt from section 502(f)(1) if all the following conditions are met:

(a) The drug is:

(1)(iii) In the possession of a practitioner licensed by law to administer or prescribe such drugs; and,

(2) It is to be dispensed in accordance with section 503(b)

Source: Title 21 CFR 201.100